

### **REMARKS**

In the Office Action, the Examiner noted that the claims 1, 3, 7-13, 18-25 and 27 are pending in the application and that the claims 1, 3, 7-13, 18-25 and 27 are rejected. By this response, claims 1, 9, 12, 13 and 27 have been amended. Thus, claims 1, 3, 7-13, 18-25 and 27 remain pending in the application. Applicants believe no issue of new matter should arise and entry of amendment is respectfully requested. Applicants respectfully traverse the rejections for the reasons indicated below.

#### ***First & Second Rejections under 35 U.S.C. § 112, first paragraph***

Claims 1, 3, 7-13, 18-25 and 27 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description and enablement requirements. While Applicants are of the opinion that the claims are adequately supported by the specification, Applicants have amended the claims to further clarify the invention.

With respect to the above claims, the Examiner asserts that the identity and amount of impurities is unknown. The Examiner also argues that the specification, while being enabling for basic zinc carbonate, does not reasonably provide enablement for an impurity containing basic zinc carbonate. Applicants have amended claim 1 to recite “wherein the zinc is incorporated in the layers of the zinc-containing layered material, and wherein the zinc-containing layered material is selected from a group consisting of basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof,” and support for the amendment can be found, for example, at paragraphs [0030]-[0031].

Accordingly, Applicants respectfully submit that the claims satisfy the requirements under 35 U.S.C. § 112, first paragraph. Withdrawal of this rejection is respectfully requested.

***Rejection under 35 U.S.C. § 103(a)***

Claims 1, 3, 7-13, 18-25 and 27 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Gavin et al. (WO 01/000151), hereafter “Gavin,” and Bhat et al. (WO 96/25913), hereafter “Bhat.” Applicants have amended the claims to further emphasize the invention.

The Examiner considers Gavin to disclose elements recited in the claims identified above. Gavin does not disclose an antimicrobial composition including “from 0.001% to 10% of a zinc-containing layered material, wherein the zinc is incorporated in the layers of the zinc-containing layered material,” as taught by amended claim 1. In contrast, Gavin teaches a composition that includes zinc pyrithione and a metal ion source such as zinc acetate, zinc oxide, zinc carbonate, zinc hydroxide, zinc chloride, zinc sulfate, zinc citrate, zinc fluoride, zinc iodide, zinc lactate, zinc oleate, zinc oxalate, zinc phosphate, zinc propionate, zinc salicylate, zinc selenate, zinc silicate, zinc stearate, zinc sulfide, zinc tannate, zinc tartrate, zinc valerate, zinc gluconate, and zinc undecylate. (Page 4, lines 18-29; Page 5, lines 27-28; & Page 6, lines 1-6) Gavin’s composition does not include a zinc-containing layered material. Although Gavin teaches that the composition can further include a surfactant, Gavin does not teach a “ratio of surfactant to the zinc-containing layered material [of] at least 2 to 1,” as further recited amended claim 1.

The Examiner admits that Gavin does not expressly teach a composition comprising a zinc-containing layered material, but argues that Bhat remedies Gavin’s deficiencies. In particular, the Examiner argues that Bhat teaches the synergistic action of zinc hydroxycarbonate with antidandruff actives like zinc pyrithione in shampoos and that one skilled in the art would be motivated to combine zinc salts of Gavin’s composition with Bhat’s composition. Applicants respectfully disagree with the Examiner.

Bhat recognizes that zinc hydroxycarbonate is also an antimicrobial compound, and has “surprisingly found that when [it] comes into contact with the skin or with the saliva in the mouth, or the microflora of the skin, scalp or hair, the zinc hydroxycarbonate in the presence of a surfactant such as soap and/or synthetic detergent shows a synergistic enhancement of the

antimicrobial effect.” (Page 2, lines 19-26) Bhat hypothesises that the “zinc hydroxycarbonate, not being soluble in water, is substantive to the skin, mucous membranes, hair, mould and microbial cell walls particularly wherever there is any acid site, and upon neutralising the acid site delivers divalent zinc ions which act on microbes which generate acids such as butyric and lactic acids.” (Page 2, lines 28-35) Although Bhat provides a single reference to a combination of zinc hydroxycarbonate with zinc pyrithione as providing a synergistic effect, Bhat has neither provided any evidence nor even hypothesized that the addition of zinc pyrithione enhances the acid neutralizing action of zinc hydroxycarbonate at the microbial cell wall site. As concluded by Bhat, it is the surfactants, e.g. soap and/or synthetic detergents, that place the zinc hydroxycarbonate onto the desired spot, thereby providing a synergistic effect in antimicrobial activity. (Page 2, lines 35-37) In view of Bhat’s hypothesis, one skilled in the art would not rely on additional components such zinc salts to enhance the zinc hydroxycarbonate-surfactant synergistic combination.

Further, Gavin is concerned with reducing the levels of metal pyrithiones in the composition. (Page 3, lines 10-13) Gavin teaches that the metal ion source enhances the biocidal effect of the anti-microbial particulate, such as zinc pyrithione, and allows for the reduction of the levels of zinc pyrithione in the composition. (Page 3, lines 10-13 & Page 4, lines 7-8) Nothing in Gavin suggests adding zinc-containing layered material to its composition in order to provide an acid neutralizing action at the microbial cell wall site.

Similar arguments apply for independent claim 27.

Therefore, the combination of Gavin and Bhat do not meet the claim limitations recited in independent claim 1. Claims 3, 7-13 and 18-25 depend directly or indirectly from claim 1, and are deemed to be allowable for reasons including those discussed above. Accordingly, Applicants respectfully submit that the claims satisfy the requirements under 35 U.S.C. §103(a). Withdrawal of this rejection is respectfully requested.

***Double Patenting***

Claims 1, 3, 7-13, 18-22 and 25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1, 2, 8-12, 16-32 and 34-39 of co-pending U.S. Application No. 11/602,770 ("the '770 application"). While the Applicants are of the opinion that claims 1, 3, 7-13, 18-25 and 27 differ from claims 1, 2, 8-12, 16-32 and 34-39 of the '770 application, Applicants have submitted on October 19, 2012 a terminal disclaimer in compliance with 37 C.F.R. 1.321(d) to overcome the provisional rejection based on the doctrine of nonstatutory obviousness-type double patenting rejection. Withdrawal of this rejection is respectfully requested. In an Advisory Action mailed October 31, 2012 the Examiner notes the filing of this terminal disclaimer on October 19, 2012 over copending 11/602770. The Examiner stated that the TD has not yet been processed.

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**Conclusion and Authorization**

In view of the above amendments, Applicants believe the pending application is in condition for allowance. Early and favorable action is requested.

Respectfully submitted,

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